Administrative Detention that Replaces Referral to State	0 to 23	0 to 30	$0 to $9 M
Total			$0 M to $156 M

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Costs of Marking or Labeling

We might label or mark food that we have administratively detained. If we were to label or mark food that we have administratively detained, we could do so in several ways, including, but not limited to, affixing a tag having a self-locking pin that would be inserted in an appropriate seam, border, flap, or other area of the container or product; taping or tying a tag firmly onto the container or item; or affixing the tag to the accompanying documents, or to the carrier. However, if we subsequently cancelled the administrative detention order, then either we, or the firm, would need to remove the label or mark. Class I recalls do not involve marking or labeling. Moving directly to a seizure action or referring a ~~problem~~ matter to state authorities also does not involve marking or labeling prior to the seizure action.

4-25 66 should include

In an analysis of another proposed rule that we published in

2001, we discussed the costs of marking cartons of imported food with printed labels that we could affix with label guns. (Ref. 8) In that analysis, we assumed that an average shipment of imported food would contain about 300 cartons or containers. We estimated that the cost of the labor time necessary to attach the labels would be $53 (three hours at $17.64 per hour), and that the cost of labels would be $13 (300 labels at $0.025 per label). A shipment of imported food can involve any number of lines of imported food. Therefore, we assume that one line could contain between 1 and 300 cartons. We earlier assumed that the average amount of food in a line is 15,000 pounds. Therefore, an administrative detention action involving between 0 and 1 million pounds would require 0 to 200 hours of labor time, and 0 to 20,000 labels. The cost of the labor time necessary to attach the labels would be $0 to $3,500, and the cost of the labels would be $0 to $900.

We assume that the costs associated with the type of labeling we would require for administrative detention would be similar to the costs associated with the type of labeling we discussed in the 2001 analysis. We also assume it would take the same amount of labor time to remove the labels, if we canceled the administrative detention order, as it would take us to affix the labels. We request comments on these assumptions. Under

the proposed rule, we would attach the labels, and firms, under our supervision, would remove the labels, if we terminated the detention order, or when the detention order expired.

After rounding to the nearest million, we estimate the cost for additional marking or labeling would be $0 ~~M~~ to $1 ~~M~~.

Table ~~6~~5 - Marking or Labeling			
Action ~~Replaced by Administrative Detention~~	**Number of ~~Substitutions~~ Actions**	**Label Cost per ~~Substitution~~ Action**	**Change in Total Loss of Value (rounded to nearest million $)**
~~No preliminary action (move directly to seizure)~~ Administrative Detention that Replaces Case of Moving Directly to Seizure	0 to 16	$4,400 to $7,933	$0 ~~M~~
~~Class I recall~~ Administrative Detention that Replaces Class	0 to 184	$4,400 to $7,933	$0 to $1 ~~M~~

I Recall			
Administrative Detention that Replaces Referral to State	0 to 23	$4,400 to $7,933	$0 ~~M~~
Total			$0 ~~M~~ to $1 ~~M~~

Costs of Appeals ~~and Other Enforcement Costs~~

The appeals process associated with administrative detention actions is another potential source of costs. ~~Again, in~~ In order to calculate the costs of administrative detention actions relative to the other baseline enforcement actions, we must first consider the cost of appeals associated with the other actions. There is no ~~formal~~ appeals process associated with Class I recalls because these are voluntary. There is often an informal dialogue between firms ~~that~~ we request to take Class I recalls ~~and FDA~~. However, this type of dialogue ~~may~~ take place with respect to any enforcement activity, including administrative detentions and seizures. Therefore, we have not included the costs of this informal dialogue ~~as~~ part of the baseline costs. Based on these assumptions, our estimate of the appeals costs for administrative detentions that replace Class I recalls is simply the total costs associated with appeals of administrative

detentions.

There is also no appeals process prior to a seizure action in cases in which we move directly to a seizure action. However, firms can contest seizure actions, once they occur. In addition, firms can appeal federal district court resolutions of ~~our decisions on~~ contested seizure actions. Most recently, f~~F~~irms have contested approximately 65~~80~~ percent of our seizure actions involving foods. However, firms rarely ~~only~~ appeal federal district court resolutions of ~~our decisions on~~ contested seizure actions ~~on an irregular basisabout one every two years~~. Previously, we noted that we would not include the costs associated with seizure actions in baseline costs. This is because we might follow an administrative detention with a seizure action, so any costs associated with seizure actions might take place irrespective of whether those seizure actions were preceded by administrative detentions. Instead, we viewed administrative detentions as preliminary enforcement actions that had no counterpart in cases in which we moved directly to a seizure action. However, in this instance, we have included our costs associated with contested seizure actions as part of baseline costs. We have included these costs because firms that appeal an administrative detention, and lose that appeal, are probably ~~may beare probably significantly~~ less likely to contest

a subsequent seizure action, than firms that are involved in a seizure action that was~~we did~~ not preceded by ~~with~~ an administrative detention. Therefore, the appeals process for administrative detentions may, as a practical matter, replace the process of contesting seizure actions in many cases in which we administratively detain food and then seize it. On the other hand, we have not included the costs associated with appealing federal district court resolutions of ~~our decisions on~~ contested seizure actions as part of baseline costs. These types of appeals are quite rare, and estimating the costs associated with these types of appeals would have little impact on our cost estimates.

Finally, there is no appeals process associated with referring a ~~problem~~ matter to state authorities. Of course, if state authorities subsequently take enforcement action, then various appeals processes may be available under state laws or regulations for those actions. However, those methods of appeal would be available irrespective of whether the state actions were preceded by administrative detentions. In addition, the variety of state actions and appeals processes suggests that the probability that a firm will appeal a state action is probably not highly related to whether it has already filed and lost an appeal of an administrative detention. Therefore, we assume that

administrative detention will not affect the probability that firms will appeal subsequent state actions.

We estimate that our costs for activity related to appeals of administrative detentions would be approximately $50,000 to $70,000 per administrative detention. We based that estimate on our costs for preparing for possible appeals, which would be generated by all administrative detention actions, and our costs for participating in appeals hearings, which would be generated only by those administrative detentions that result in hearings. In order to calculate an average cost per administrative detention action, we assumed that 6580 percent of our administrative detentions would result in an appeals hearing. We based that assumption on the proportion of seizure actions that firms contest. Therefore, the incremental change in appeals costs associated with substituting an administrative detention action for a Class I recall is approximately $530,000 to $760,000.

Our costs for activity related to firms contesting our seizures are approximately $10,000 to $20,000 per seizure action. We based that estimate on our costs for participating in a contested seizure case, and ~~a~~an ~~50 to~~ 6580 percent chance that firms would contest any given seizure action. Therefore, the incremental change in appeals costs associated with substituting

an administrative detention action for a case of moving directly to a seizure action is approximately $30,000 to $60,000. We present the resulting cost estimates for the agency in Table 6. of this document

Table 6 - Appeals			
Action	**Number of Actions**	**Appeals Costs per Action**	**Total Appeals Cost (rounded to nearest million $)**
Administrative Detention that Replaces Case of Moving Directly to Seizure	0 to 16	$30,000 to $60,000	$0 to $1 M
Administrative Detention that Replaces Class I Recall	0 to 184	$50,000 to $70,000	$0 to $13 M
Administrative Detention that Replaces Referral to State	0 to 23	$50,000 to $70,000	$0 to $2 M
Total			$0 M to $16~~14~~ M

A firm's decision to appeal an administrative detention order is voluntary. A firm would only appeal an administrative

detention order if the costs of doing so were less than the costs of not doing so. Therefore, a firm's participation in the appeals process would usually reduce the costs that we previously estimated for storage and value loss by more than the cost of participating in the appeals process. Because we have already estimated storage costs and product value loss as a range that goes to zero, we have not attempted to analyze the cost and benefit implications of firms' decisions to appeal administrative detention actions.

The specific characteristics of the proposed appeals process for administrative detentions would affect the cost of the appeals process for us and for affected firms. Examples of specific characteristics include the time frame under which we would allow firms to file an appeal for perishable and non-perishable food, the information we would require in an appeal, the timeframes in which we would respond to an appeal, and the availability of an appeals hearing, as opposed to some other type of appeals process. We request comments on the impacts of the specific requirements of the proposed appeals procedure.

Other Enforcement Costs

Differences in ~~the~~ other enforcement costs associated with administrative detention actions, class I recalls, ~~and~~ moving directly to seizure actions, and referring ~~problem~~matters to state authorities, are also relevant to this analysis. Both administrative detentions and Class I recalls require us to undertake certain types of activity to implement, and we assume that the costs of this activity would be similar for these actions. Although taking no action prior to a seizure action or to referring a ~~problem~~ matter to state authorities~~, does not~~ requires no~~any~~ activity, the activity that we undertake to move directly to seize food or to provide information on a ~~problem~~ matter to state authorities probably overlaps to some degree with the activity that we would undertake to implement an administrative detention action. The cost of the additional activity required to seize food following another enforcement action is significantly less than the cost of the activity required to move directly to seize food, because some of the activity of the preliminary action is also relevant to seizing the food. Therefore, we assume that the cost of the activity that we undertake to directly move to seize food is similar to the cost of the activity we undertake to implement an administrative detention action followed by a seizure action. Similarly, we assume that the cost of the activity that we and

states undertake when we refer a ~~problem~~ matter to state authorities is similar to the cost of the activity that we and states undertake to implement an administrative detention action followed by state action.~~, or a combination of an administrative detention action and a seizure action~~.

~~There is no appeals procedure associated with Class I recalls, because they are voluntary. However, firms that we request to perform recalls may nevertheless take some of the same actions that they might take if they were to appeal an administrative detention order. For example, they might assemble and present material disputing the basis of our recall request. Therefore, we assume that substituting an administrative detention action for a Class I recall request would not generate additional costs due to the appeals procedures for administrative detention. We request comments on this assumption.~~

~~Moving directly to a seizure action would not involve an appeals procedure prior to the seizure, although a firm might, of course, appeal the seizure. As we discussed previously, we might follow an administrative detention action with a seizure action. Therefore, the cost of the appeal procedures associated with administrative detention would be in addition to the cost of the appeal procedures associated with the seizure action. A firm's decision to appeal an administrative detention order is~~

~~voluntary. A firm would only appeal an administrative detention order if the costs of doing so were less than the costs of not doing so. Therefore, the availability of an expedient appeals procedure for administrative detention would reduce the costs that we previously estimated for storage and value loss to some degree. However, FDA would also undergo certain costs to administer and participate in the appeals procedure. These costs would be an additional cost beyond the costs that we previously discussed. We tentatively assume that these cost savings and costs would be roughly comparable in size, and would essentially cancel each other out.~~

~~The specific characteristics of the proposed appeals process for administrative detention would affect the cost of the appeals process for us and for affected firms. Examples of specific characteristics include the time frame under which we would allow firms to file an appeal for perishable and non perishable food, the information we would require in an appeal, the time frames in which we would respond to an appeal, and the availability of an appeals hearing, as opposed to some other type of appeals process. We request comments on the impacts of the specific requirements of the proposed appeals procedure.~~

~~In terms of discussing social costs, which is the primary focus of this analysis, it does not matter whether costs are~~

~~borne by us or by firms. However, in terms of the distributional impact of this rule, we would bear the enforcement costs (which may include the cost of supervising or observing transportation or other actions on the part of firms), the costs of preparing for appeals, and the cost of administering appeals. Firms would bear the costs of preparing and submitting appeals, and participating in the appeals process. The need for a firm to appeal an administrative detention order in order to avoid an even greater loss due to storage costs and loss of value is also a distribution effect that may be an important consideration, particularly if we later determine that the administratively detained food were not violative.~~

Cost Summary

We present a summary of the costs in Table 7 of this document.

Table 7 - ~~Total Annual Costs~~ Annual Costs for Option 1: Transportation and Perishable Foods (Proposed Rule)	
Type of Cost	**Cost** (in millions)
Transportation	$0 ~~M~~ to $~~3~~24 ~~M~~
Storage	$0 ~~M~~ to $~~1~~2 ~~M~~

Loss of Product Value	$0 M to $156 M
Marking or Labeling	$0 M to $1 M
Appeals	$0 M to $1614 M
Total	$0 M to $113824 M

Benefits

Administrative detention authority improves our ability to respond to outbreaks from accidental and deliberate contamination from food, and deter deliberate contamination. Based on historical evidence, a strike on the food supply has a very low probability, but would be a potentially high cost event. FDA lacks data to estimate the likelihood and resulting costs of a strike occurring. Without knowing the likelihood or cost of an event, we cannot quantitatively measure the reduction in probability of an event occurring or the possible reduction in cost of an event, associated with each regulatory option. Further hindering any quantification of benefits is the interactive effect of the other regulations that are being developed to implement Title III of the Bioterrorism Act.

Administrative detention differs from existing enforcement alternatives along the following dimensions: 1) speed of action; 2) need for collaboration with other agencies; 3) maximum level of security; and 4) time frames. Actions that we can implement

faster will reduce risk more than actions that take longer to implement, because we have a higher probability of removing the product from commerce before it reaches the consumer. We have a higher probability of successfully taking an action that does not require collaboration because actions that require us to collaborate with other agencies involve more than one set of decision criteria and more than one decision maker. Actions that allow us to require higher security transportation and storage reduce risks because such actions reduce the probability that we will lose control of the product, and that adulterated food will reach consumers. Actions with longer time frames reduce risk because we have more time to complete our investigation and a lower probability of releasing food that is violative back into commerce. The relative advantages of the various enforcement actions are provided in Table 8. The expressions "permanent" and "temporary~~medium~~" in the time frames represent the relative time frames under which we can keep a potentially violative food out of the distribution system.

Table 8 - Comparison of Enforcement Actions				

Action	Speed	Collaboration	Highest Potential Security	Time Frames
Administrative Detention	High	No	High	~~Medium~~Temporary
Seizure	Low	No	High	Permanent
Class I Recall	Low~~Medium~~	Yes	Low	Permanent
Referral to state	Low	Yes	Low	Unknown

We have insufficient information to quantify the health benefits of substituting administrative detention for the other enforcement actions. However, to understand the possible costs of an intentional strike on the food supply, Table 9 presents information on five outbreaks resulting from accidental and deliberate contamination, involving both domestic and imported foods. These outbreaks do not represent possible forms that a terrorist attack might undertake, but merely illustrate the public health costs of foodborne disasters. It is likely that an intentional attack on the food supply that sought to disrupt the food supply and sicken many U.S. citizens would be much larger. However, the probability of an attack occurring and the exact reduction in risk resulting from administrative detention is unknown.

Table 9—Summary of five foodborne outbreaks

Pathogen	**Location and Year**	**Vehicle**	**Confirmed or reported cases**	**Estimated number of cases**	**Total illness cost**
Salmonella enteritidis	Minnesota 1994	Ice cream	150 cases; 30 hospital-ized	29,100 in MN; 224,000 Nationwide	$3,187,744,000 to $5,629,792,000
Shigella sonnei	Michigan 1988	Tofu salad	3,175 cases	Not available	$45,183,000 to $79,797,000
Outbreaks resulting from deliberate contamination					
Salmonella Typhimurium	Dalles, Oregon 1984	Salad bars	751 cases; 45 hospital-ized	Not available	$10,687,000 to $18,875,000
Shigella dysentre-riae type 2	Texas 1996	Muffins and dough-nuts	12 cases; 4 hospital-ized	All cases identified	$83,000
Outbreaks resulting from imported foods					
Cyclospora cayaeta-nensis	United States and Canada 1996	Rasp-berries (probably imported from Guatemala)	1465 cases identi-fied, less than 20 hospital-ized	Not available	$3,941,000

***Salmonella enteritidis* in ice cream**

In 1994, approximately 224,000 people were sickened by ice

cream contaminated with Salmonella enteritidis. The source of the contamination appeared to be pasteurized pre-mix that had been contaminated during transport in tanker trailers that carried non-pasteurized eggs. There were 150 confirmed cases of salmonellosis associated with the outbreak in Minnesota. However, ice cream processed during the contamination period was distributed to 48 states. To calculate the total number of illnesses associated with the outbreak, researchers calculated an attack rate of 6.6 percent. This attack rate was extrapolated to the population that consumed the ice cream, giving a total number sickened of 224,000. (Ref. 9)

Salmonellosis most commonly causes gastrointestinal symptoms. Almost 91 percent of cases are mild and cause one to three days of illness with symptoms including diarrhea, abdominal cramps, and fever. Moderate cases, defined as cases that require a trip to a physician, account for 8 percent of the cases. These cases typically have a duration of two to 12 days. Severe cases require hospitalization and last 11 to 21 days. In addition to causing gastroenteritis, salmonellosis also can cause reactive arthritis in a small percentage of cases. Reactive arthritis may be short or long term and is characterized by joint pain. Just over one percent of cases develop short-term reactive arthritis and two percent of cases develop chronic, reactive arthritis.

FDA estimated the costs associated with salmonellosis, including medical treatment costs and pain and suffering. Table 10 provides a summary of these estimates. Pain and suffering is measured by lost quality adjusted life days (QALDs). QALDs measure the loss of utility associated with an illness. A QALD is measured between zero and one, with one being a day in perfect health. ~~The total loss of a Quality Adjusted Life Year (QALY), or the loss of a year of life is valued at $100,000, based on economic studies of how consumers value risks to life. (Ref. 10) Thus, an entire lost QALD would be valued at $274 and fractions of QALDs are a fraction of the day's value.~~ FDA presents two estimates of values of pain and suffering associated with arthritis, one based on physician estimates (Ref. 11) and another based on a regression analysis approach (Ref. 12). This gives a range of costs for the average case of salmonellosis between $14,231 and $25,133.

Severity	Case Breakdown	Total QALDs Lost per Illness	Health Loss per Case (Discounted)	Medical Costs per Case (Discounted)	Weighted Dollar Loss per Case
Illness					
Mild	90.7%	1.05	$660	$0	$599
Moderate	8.1%	3.68	$2,310	$283	$209
Severe	1.2%	9.99	$6,266	$9,250	$188
Arthritis					
Regression Approach					
Short-Term	1.26%	5.41	$3,391	$100	$44
Long-Term	2.40%	2,613.12	$452,554	$7,322	$11,048
Direct Survey Approach					
Short-Term	1.26%	10.81	$6,778	$100	$87
Long-Term	2.40%	5,223.15	$904,573	$7,322	$21,906
Death	0.04%		$5,000,000		$2,143
Total Expected Loss per Case				*Regression Approach*	$14,231
				Direct Survey Approach	$25,133

Table 10: The value of a typical case of salmonellosis

To estimate the economic cost due to illness associated with this outbreak, FDA used the range for the average cost per case. For 224,000 people, this is a total cost of between $3,187,744,000 and $5,629,792,000 from this accidental food disaster.

***Shigella sonnei* in tofu salad**

In 1988, a tofu salad at an outdoor music festival was contaminated with Shigella sonnei and sickened an estimated 3,175 people. Over 2,000 volunteer food handlers served communal meals at the festival. (Ref. 13) Shigellosis causes similar symptoms and is of similar duration to salmonellosis. It also is associated with short term and chronic reactive arthritis; thus FDA assumed the average case of shigellosis has the same cost as salmonellosis. This gives a total cost of $45,183,000 to $79,797,000.

***Salmonella typhimirium* in salad bars**

During September and October of 1984, two outbreaks of Salmonella typhimirium occurred in association with salad bars in restaurants in The Dalles, Oregon. At least 751 people were affected. Members of the local Rajneeshpuram commune intentionally caused the outbreak by spraying Salmonella typhimirium on the salad bars in local restaurants. Their apparent motivation was to influence a local election by decreasing voter turnout. Intentional contamination was not suspected immediately and no charges were brought until a year after the attacks. (Ref. 14)

The 751 people affected primarily were identified through

passive surveillance; thus the true number of people actually sickened is undoubtedly much higher. The Dalles is located on Interstate 84 in Oregon and is a frequent stop for travelers who were unlikely to be identified by passive or active surveillance for salmonellosis. However, since we do not have any estimates of the true size of the outbreak, we estimated the costs associated with known cases, recognizing this is an underestimate of the true cost of the outbreak. We use the cost estimates for salmonellosis as ranging from $14,231 to $25,133. This gives an estimated cost of known cases for the outbreak of $10,687,000 to $18,875,000.

***Shigella dysenteriae* type 2 among laboratory workers**

Twelve people working in a laboratory who consumed muffins left in the laboratory break room contracted shigellosis. Affected workers had diarrhea, nausea, and abdominal discomfort. Investigators concluded that the outbreak likely was the result of deliberate contamination. All twelve affected workers were treated by, or consulted with, a physician. Nine affected workers went to the emergency room, four of whom were hospitalized. (Ref. 15)

To estimate the cost of this outbreak, FDA assumed that the eight cases requiring consultation with a doctor, but not

requiring hospitalization, had the same cost as a moderate case of salmonellosis. The four cases requiring hospitalization were estimated to have the same cost as a severe case of gastroenteritis resulting from salmonellosis. This gives a cost of $83,000 for illnesses associated with the event.

Table 11: Summary of costs for cases of shigellosis

Severity	Number of cases	Cost per case	Total cost
Mild	0	$0	$0
Moderate	8	$2,593	$21,000
~~Severe~~	~~4~~	~~$15,516~~	~~$62,000$62,06~~ ~~4~~
Severe	4	$15,516	$62,000
			$83,000

***Cyclospora cayatanensis* in imported raspberries**

In 1996, 1,465 cases of cyclosporiasis were linked to consumption of raspberries imported from Guatemala. Nine hundred and seventy eight of these cases were laboratory confirmed. No deaths were confirmed and less than 20 hospitalizations were reported. (Ref. 16) Case control studies indicated that raspberries imported from Guatemala were the source of the illnesses. Fifty-five clusters of cases were reported in 20 states, two Canadian provinces, and the District of Columbia. (Ref. 17)

Cyclosporiasis typically causes watery diarrhea, loss of

appetite, weight loss, and fatigue. Less common symptoms include fever, chills, nausea, and headache. The median duration of illness associated with the outbreak was more than 14 days and the median duration of diarrheal illness was 10 days. (Ref. 17)

We estimated the cost of a mild case of cyclosporiasis as two and a half times higher than the cost of a mild case of gastroenteritis from salmonellosis due to the longer duration. The reports of cyclosporiasis outbreaks did not include information on the number of physician visits. We assumed that the percentage of total cases that result in physician visits would be larger than the corresponding percentage for salmonellosis illnesses, due to the longer duration of illnesses. We assumed, therefore, that 40 percent of those infected with cyclosporiasis visited a physician. Less than 20 hospitalizations were reported from the cyclosporiasis outbreak. (Ref. 16) No deaths were confirmed.

Table 12: Summary of costs for cases of cyclosporiasis

Severity	Number of cases	Cost per case	Total cost
Mild	879	$1,650	$1,450,000
Moderate	586	$3,748	$2,196,000
Severe	19	$15,516	$295,000
			$3,941,000

Option Two: Take the proposed action, but change either or both the definition of perishable food and the maximum time frame for administrative detention of perishable food

Costs

If we established a shorter maximum time frame for administrative detention of perishable food, then we would reduce the potential storage costs and loss of value associated with administratively detaining that food. If we also broadened the definition of perishable food to include products with a shelf life of over seven days, then we would further decrease the storage costs and loss of food product value for those additional types of food. One reasonable alternative would be to broaden the definition of perishable food to include any food that might lose all of its value during a 30 day administrative detention period, that is, any food with a shelf life of 30 days or less, and reduce the maximum time frame for administratively detaining a perishable food to 14 days. We calculated the costs of this option using the same procedures that we used for Option One (take the proposed action). We present these costs in Table 13.

Table 13- Annual Costs for	**Cost (rounded to nearest**

Option 2: Alternative Definition and Maximum Detention Period for Perishable ~~Domestic~~ Food	**million $)**
Type of Cost	
Transportation Cost	$0 ~~M~~ to $~~423~~ ~~M~~
Storage Cost	$0 ~~M~~ to $1 ~~M~~
Loss of Product Value	$0 ~~M~~ to $~~83~~ ~~M~~
Marking or Labeling	$0 ~~M~~ to $1 ~~M~~
Appeals	$0 ~~M~~ to $~~1614~~ ~~M~~
Total	$0 ~~M~~ to $~~23018~~ ~~M~~

If we attempted to maintain the same level of investigation under the shorter maximum time frames for perishable food by using our enforcement resources more intensively, then enforcement costs might also increase. In that case, we would need to compare the cost of using our investigative resources more intensively for a shorter period of time relative to using those resources less intensively for a longer period of time. More intensive use of resources would probably cost more because it would probably require our employees to work overtime and possibly over weekends and holidays. Therefore, this would reduce any cost savings introduced by the shorter maximum time frames for perishables.

Benefits

Changing the definition of perishable food and the maximum time frames for administrative detentions of perishable food could also affect the health benefits of this rule. Broadening the definition of perishable food and establishing a shorter maximum time frame for administratively detaining that food would reduce the maximum time frames for storage of those products that qualified as perishable food relative to the time frame for non-perishable food. The significance of this change depends on how often we need the full 30 days to complete our investigations. If we usually complete our investigations in the time allowed under the hypothetical shorter maximum detention time we could establish for perishable food, then including more products in the perishable category would have little effect on the risk that we would fail to catch a violative product because of the shorter investigation period. However, if we often need the full 30 days to complete our investigations, then including more products in the perishable category and establishing a shorter maximum detention time for administrative detention of perishable food would increase the risk that we would fail to catch a violative product during the investigation period. We do not have sufficiently detailed information to estimate these changes in

health benefits.

We might also be able to maintain the same effect on risk and health benefits under the shorter time frames by using resources more intensively during the shorter investigation period. For example, if we were to allocate more employees to work on an investigation, or if our employees were to work extra hours, then we might be able to complete the same level of investigation under a shorter time frame. In that case, this option would have the same health benefits as Option One, but additional costs might be generated by the more intensive use of resources.

Option Three: Take the proposed action, but change the level of security we require for transportation and storage.

Costs

Instead of judging the need for various levels of security on a case-by-case basis, we could require firms to use specified levels of security to transport and store food under specified conditions. In Option One, we assumed, based on information from a trade group, that the costs for using bonded carriers and warehouses were similar to those for using non-bonded carriers

and warehouses. However, if we chose a lower security approach and allowed firms to store administratively detained food in place, then we would eliminate the transportation costs. Eliminating transportation costs would reduce total costs to a range of $0 ~~M~~ million to $~~53422~~ M.

If we required firms to undertake security operations they would not otherwise have taken, then we would need to add in the cost of that activity. One example of the type of activity we might require is posting additional security guards. The average hourly wage of a security guard in 2000 was about $9.50. (Ref. 18) We doubled this wage to account for overhead, such as health benefits, to get an annual hourly wage of about $17. Therefore, the average cost of posting one additional security guard would be approximately $450 per day. The number of guards would depend on the number of facilities involved. Firms might already have distributed food that we administratively detain. Based on our experience with other enforcement actions, we believe that between one and twenty storage facilities might be involved per administrative detention action. Therefore, we calculate the cost of adding one guard by multiplying the cost of one additional security guard per day, times a maximum of 30 days storage, times the number of administrative detentions, times the number of facilities involved per administrative detention.

Using this approach, we estimate the total costs associated with no transportation and posting one additional guard would be $0 M to $45412 M.

Table 14 – Annual Costs for Option 3: No Transportation and One Additional Guard	
Type of Cost	(rounded to nearest million $)
One additional guard	$0 M to $114 M
Storage Cost	$0 M to $21 M
Loss of Product Value	$0 M to $156 M
Marking or Labeling	$0 M to $1 M
Appeals	$0 M to $1614 M
Total	$0 M to $245612 M

We do not have information on the costs of using high security transportation and storage. However, requiring high security transportation and storage would probably substantially increase transportation and storage costs.

Benefits

As discussed in Option One, bonded and third party carriers and warehouses provide some degree of additional security relative to relying on a firm's own transportation system and storage facilities. However, they do not provide the highest

level of security because food can be stolen from such facilities, and because the owners of those facilities could, themselves, become involved in deliberately adulterating food. Therefore, requiring a higher level of security for transportation and storage would reduce the probability that an adulterated product might find its way back into commerce during a detention. We have insufficient information to estimate the change in health benefits from more secure transportation and storage.

Option Four: Promulgate regulations only to establish expedited procedures for instituting certain enforcement actions involving perishable food (i.e., limit the action to that required by Section 303 of the Bioterrorism Act)

The Bioterrorism Act requires us to promulgate regulations establishing expedited procedures for instituting ~~perishable food for~~ seizure actions, injunction actions, or both against perishable food. Therefore, taking no regulatory action with regard to those procedures would not be a legally viable option. However, we could promulgate a more limited rule that covered only expedited procedures for enforcement actions involving perishable food, rather than a rule that also included general

procedures for administrative detention.

Costs

If we were to promulgate a more limited rule, we would still be able to administratively detain food because Congress has already granted us that authority under the Bioterrorism Act. We would probably administratively detain food in the same situations in which we would have taken this action under the proposed rule. Therefore, the costs we estimated under Option One would also apply to this option. In addition, there could be some additional enforcement cost associated with relying on the language of the Act rather than our own regulations when taking this action. These additional costs would be caused by our need to develop and defend our interpretation of the language of the Bioterrorism Act piecemeal in court, rather than through implementing regulations. These court proceedings would probably take longer and be more complicated than they would be, if we were enforcing more specific regulatory language. We have insufficient information to estimate this change in costs. Therefore, we can only determine that the lower bound of the range of potential costs for this option would be somewhat greater than $0 M, and the upper bound would be somewhat higher

than $~~11~~3824 ~~M~~ million, and the costs associated with this option would be somewhat greater than those associated with Option One under any given scenario.

Benefits

Again, even if we did not include the overall framework for administrative detention in this rule, we would probably use administrative detention in the same situations in which we would use administrative detention under the framework developed in this proposed rule. However, we expect we would have somewhat more difficulty using administrative detention if we relied only on the language of the Act rather than also on our more detailed regulations. ~~In some cases, it might take us longer to institute an administrative detention through court proceedings than it would take us to do so through regulatory action~~because ~~of pending the expense and delay of the court proceedings, we may not be able to use administrative detention in other situations might delay our enforcement actions under the Act, which would reduce the benefits that would have followed from more timely action in those other situations.~~ For example, if we needed to develop and defend our interpretation of the language of the Bioterrorism Act piecemeal in court, ~~we may not be able~~ our

ability to pursue administrative detentions while ~~we are engaged in~~ such proceedings are ongoing might be limited or even precluded. Therefore, the benefits of this option might be somewhat lower than those for Option One.

Summary of Options

We summarize the costs and benefits of the various options in Table 15.

Table 15- Summary of Annual Costs and Benefits		
Option	**Costs** (in millions)	**Benefits** (in millions)
1 - transportation and perishable foods as proposed	$0 ~~M~~ to $~~11~~3824 ~~M~~	> $0 ~~M~~
2 - perishable foods alternatives	$0 ~~M~~ to $~~230~~18 M	> $0 ~~M~~, but < Option 1
3 - no transportation, but one additional guard	$0 ~~M~~ to $~~12~~4526 ~~M~~	> $0 ~~M~~
4 - limited to the Bioterrorism Act	>$0 ~~M~~ to >$~~11~~3824 ~~M~~	> $0 ~~M~~, but < = Option 1

The ranges generated by the underlying uncertainties in our

analysis, particularly concerning benefits, precludes us from drawing any firm conclusions about the relative net benefits of the various regulatory options. The potential costs for Option One (the proposed rule) are lower than those for Option Three, and we are unable to differentiate the potential benefits of these two options. The similarity between the estimated ranges of costs and benefits for these two options suggests that we should determine whether to require transportation or storage in place on a case-by-case basis, as we have proposed. The potential costs for Option One are higher than those for Option Two. However, the estimated benefits of Option One are also higher than those of Option Two. We have insufficient information to quantify the difference in benefits. The potential costs for Option One are lower than those for Option Four, and the benefits of Option One are greater or equal to those of Option Four. Therefore, Option One would lead to higher net benefits than Option Four.

B. Initial Regulatory Flexibility Analysis

We have examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. ~~SS~~

601-612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires us to analyze regulatory options that would lessen the economic effect of the rule on small entities. We ~~are unsure whether or not~~ find that this proposed rule would not have a significant economic impact on a substantial number of small entities. Nonetheless, we have provided ~~The analysis below, together with other relevant sections of this document, serves as our~~ an initial regulatory flexibility analysis under the Regulatory Flexibility Act, which consists of the analysis below together with other relevant sections of this document.

This proposed rule may affect firms involved in the production or handling of human food and animal feed such as the following: 1) food producers such as farms, ranches, fisheries, dairies, bakeries, breweries, distilleries, and manufacturers of processed food, food additives, dietary supplements, infant formula, and food contact substances; 2) food importers; 3) food wholesalers or brokers; 4) food retailers; 5) food service establishments; and 6) food transporters. The rule might affect producers because we could administratively detain food at one of the producer's facilities prior to distribution of that food to wholesalers or brokers. We could also administratively detain food anywhere in the distribution system, from wholesaler and

retailer warehouses, to retail store shelves, to food service establishment kitchens or storerooms. The rule might affect transporters because we might detain food that is en route to another location, and the food might be packed together with food that we would not detain. This might cause delays in the deliveries of the other food.

Potentially affected firms fall into a number of different North American Industry Classification System (NAICS) codes, including the following: 111 Crop Production, 112 Animal Production, 1141 Fisheries, 311 Food Manufacturing, 3121 Beverage Manufacturing, 325412 Pharmaceutical Preparation Manufacturing, 4224 Grocery and Related Products Wholesalers, 4225 Farm Product Raw Material Merchant Wholesalers, 4248 Beer, Wine, and Distilled Alcoholic Beverage Merchant Wholesalers, 445 Food and Beverage Stores, 446191 Food (Health) Supplement Stores, 481112 Scheduled Freight Air Transportation, 481212 Nonscheduled Chartered Freight Air Transportation, 482 Rail Transportation, 483111 Deep Sea Freight Transportation, 483113 Coastal and Great Lakes Freight Transportation, 483211 Inland Water Freight Transportation, 484 Truck Transportation (except 48421 Used Household and Office Food Moving, 4842201 Local Hazardous Materials Trucking, 4842203 Dump Trucking, and 4842301 Long Distance Hazardous Materials Trucking), and 722 Food Service and Drinking Places. There is

also no NAICS code for manufacturers of food contact material. However, the following NAICS codes cover some of the potentially affected firms: 322215 Non-Folding Sanitary Food Container Manufacturing, 32222 Paper Bag and Coated and Treated Paper Manufacturing, 32611 Plastics Packaging Materials and Unlaminated Film and Sheet Manufacturing, 327213 Glass Container Manufacturing, and 333993 Packaging Machinery Manufacturing. There are no NAICS codes for manufacturers of food additives or for food importers, and we assume these firms are included in the other categories.

The 1997 Economic Census lists 1.6 million establishments in these categories, excluding NAICS codes 111, 112, 1141, and 482, which are not included in the Economic Census. The 2000 County Business Patterns updates some of the numbers from the 1997 Economic Census. However, the County Business Patterns data includes only establishments with employees. In order to obtain another estimate of the number of firms using the updated data, we combined the number of establishments with employees from the 2000 County Business Patterns with an estimate of the number of establishments without employees based on the proportion of firms with and without employees in the 1997 Economic Census. This procedure also led to an estimate of approximately 1.6 million establishments in these categories, excluding NAICS codes 111,

112, 1141, and 482. An establishment without employees is an establishment that is staffed only by the owners of that establishment.

We also used the Dun and Bradstreet Market Identifiers database to get a count of the number of firms in these categories. This database uses Standard Industry Classification (SIC) codes rather than NAICS codes. SIC codes do not correspond exactly to NAICS codes. We based our estimate on all SIC codes that even partially corresponded to relevant NAICS codes. This database allows one to count firms rather than establishments, and also allows one to identify firms by both primary and secondary activities. According to this database, approximately 1.8 million firms could be affected by this rule. However, we would not be able to affect more firms in one year than the estimated number of administrative detentions that we might take in one year. In the analysis of impacts above, we estimated that we might administratively detain food between 0 and 200 times per year. Therefore, we estimate that this rule may affect between 0 and approximately 200 firms per year.

The Small Business Administration (SBA) publishes definitions of small businesses by six-digit NAICS code. (Ref. 19) Some of the NAICS codes listed above are less than six digits. In those cases, we used the range of small business

definitions for all six-digit subcategories in the relevant NAICS code. The current SBA definitions in terms of either maximum annual average receipts or number of employees are as follows: 111 ($0.75 M), 112 ($0.75 M to $10.5 M), 1141 ($3.5 M), 311 (500 to 1,000), 3121 (500 to 750), 322215 (750), 32222 (500), 325412 (750), 32611 (500), 327213 (750), 333993 (100), 4224 (100), 4225 (100), 42251 (100), 4228 (100), 445 ($6 M to $23 M), 446191 ($6 M), 481112 (1,500), 481212 (1,500), 482 (500), 483111 (500), 483113 (500), 483211 (500), 484 except 48421, 4842201, 4842203, and 4842301 ($21.5 M), 722 ($6 M to $17.5 M). We applied the relevant range of sizes to the SIC codes that at least partially corresponded to the relevant NAICS codes and found that approximately 84 to 90 percent of the firms that this rule might affect are small businesses under SBA size definitions. Therefore, we estimate that this rule may affect between 0 and 180 small businesses each year.

The potential cost per administrative detention for small entities based on taking the proposed action and the information and assumptions in the preceding impact analysis would be $20,000 to $330,000, depending on the type of product involved and the type of enforcement action that we would replace with an administrative detention, and whether or not the firm appealed the administrative detention order. However, we based this range

on a number of assumptions that are probably more reasonable when applied to average or expected costs across a large number of actions than to a single action. Thus, the actual range of potential costs for a single detention action would be much larger. In addition, the cost per firm would depend on the number of times that we detain that firm's products in a given time period. The most we can say about costs on a per firm basis is that the average expected cost per firm across all potentially affected firms would presumably be quite low, but the cost for a particular firm in a particular year could be significant, depending on a number of variables including the type and amount of product involved. ~~The possibility of high costs for some firms in some years, and the fact that nearly all affected firms are small businesses, leads us to conclude that we cannot certify that this proposed rule would not have a significant economic impact on a substantial number of small entities.~~ FDA requests comment on the impact of this proposed rule on small entities.

The fact that most of the potentially affected firms are small businesses suggests that the options that would be relevant to small businesses are the same as the options relevant for all firms discussed in the impact analysis above. Options Two and Three would both reduce the impact on small firms. However, these options would also reduce benefits, and we do not have

sufficient information to estimate the change in net benefits.

Administrative detention involves preventing the movement of food upon credible evidence or information that the food presents a threat of serious adverse health consequences or death to humans or animals. This standard is applicable without regard to the size of any business involved. Most of the businesses impacted by this proposed rule are small businesses. To provide an exemption for small businesses under this proposed rule would defeat the purposes of the statute. Accordingly, we are not providing exemptions from the requirements of this regulation to small businesses.

C. Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (Public Law 104-4) requires cost-benefit and other analyses before any rule making if the rule would include a "Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year." The current inflation-adjusted statutory threshold is $112.3 million per year. We have estimated that the total cost of the proposed rule would be no more than ~~$11~~3824 million per

year. Therefore, we have determined that this proposed rule does not constitute a significant rule under the Unfunded Mandates Reform Act.

D. SBREFA Major Rule

The Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104-121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: an annual effect on the economy of $100 million; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with the Small Business Regulatory Enforcement Fairness Act, OMB has determined that this proposed rule, when final, will not be a major rule for the purpose of congressional review.

VI. Paperwork Reduction Act of 1995

This proposed rule contains information collection

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X References (Insert) p. 142

The following references have been placed on display in the Dockets Management Branch (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. FDA has verified the Web site addresses, but is not responsible for subsequent changes to the Web sites after this document publishes in the Federal Register.

provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

These proposed information collection provisions are exempt from OMB review under 44 U.S.C. 318(c)(1)(B)(ii) and 5 CFR 1320.4(a)(2) as collections of information obtained during the conduct of a civil action to which the United States or any official or agency thereof is a party, or during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities. 5 CFR 1320(c) provides that the exception in § 1320.4(a)(2) applies during the entire course of the investigation, audit or action, but only after a case file or equivalent is opened with respect to a particular party.

~~VII~~ X. References

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VIII. Analysis of Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement has not been prepared.

X. Comments

Interested persons may submit to the Dockets Management Branch (see ADDRESSES) written or electronic comments regarding this notice by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. FDA cannot be responsible for addressing comments submitted to the wrong docket or that do not contain a docket number. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FDA notes that the comment period for this document is shorter than the 75-day period that the agency customarily provides for proposed rules that are technical or sanitary or phytosanitary (SPS) measures. FDA believes that a 60-day comment period is appropriate in this instance. Executive Order 12889, "Implementation of the North American Free Trade Agreement" (58 FR 69681, December 30, 1993), states that any agency subject to the Administrative Procedure Act must provide a 75-day comment period for any proposed Federal technical regulation or any Federal SPS measure of general application. Executive Order 12889 provides an exception to the 75-day comment period where the United States considers a technical regulation or SPS measure

of general application necessary to address an urgent problem related to the protection of human, plant, or animal health. FDA has concluded that this proposed rule is subject to the exception in Executive Order 12889.

The Bioterrorism Act states that it is intended "[t]o improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies." The provisions in this proposed rule that describe the procedures for how FDA will detain an article of food, how FDA will expedite certain enforcement actions with respect to perishable food, and the process for appealing a detention order will enhance FDA's ability to prevent distribution of food that presents a threat of serious adverse health consequences or death to humans or animals. The legislative history of the Bioterrorism Act, with respect to the regulation required by section 303 of that act, notes that the "Secretary should promptly complete such rule making" (H. Conf. Rept. No. 107-481, at 131 (2002)). This expedited timeframe reflects the urgency of the United States government's need to prepare to respond to bioterrorism and other food-related emergencies.

FDA has concluded that the urgency of this matter is sufficient justification for shortening the public comment period for this proposal to 60 days, consistent with Executive Order 12889.

FDA will not consider any comments submitted after ~~[insert 60 days after publication]~~. Due to the need to promptly complete this rulemaking, FDA does not intend to grant any requests for extensions of the comment period.

List of subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, and Reporting and recordkeeping requirements.

List of subjects in 21 CFR Part 16

Administrative practice and procedure.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 1 and 16 are amended as follows:

Part 1—GENERAL ENFORCEMENT REGULATIONS

1. The authority citation for 21 CFR part 1 is revised to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 334, 343, 352, 355, 360b, 362, 371, 374, 381, 382, 393; 42 U.S.C. 216, 241, 243, 262, 264.

2. New subpart K is added to read as follows:

Subpart K—ADMINISTRATIVE DETENTION

OF FOOD FOR HUMAN OR ANIMAL CONSUMPTION

General Provisions

Sec.

1.377 What definitions apply to this subpart?

1.378 What criteria does FDA use to order a detention?

1.379 How long may FDA detain an article of food?

1.380 Where and under what conditions must the detained article of food be held?

1.381 May a detained article of food be delivered to another entity or transferred to another location?

1.382 What labeling or marking requirements apply to a detained article of food?

1.383 What expedited procedures apply when FDA initiates a seizure action against a detained perishable food?

1.384 When does a detention order terminate?

How does FDA order a detention?

1.391 Who approves a detention order?

1.392 Who receives a copy of the detention order?

1.393 What information must FDA include in the detention order?

What is the appeal process for a detention order?

1.401 Who is entitled to appeal?

1.402 What are the requirements for submitting an appeal?

General Provisions

§ 1.377 What definitions apply to this subpart?

The definitions of terms that appear in section 201 of the Act (21 U.S.C. 321) apply when the terms are used in this subpart.

In addition, for the purposes of this subpart:

Act means the Federal Food, Drug, and Cosmetic Act.

Authorized FDA representative means an FDA District Director in whose district the article of food involved is located or an FDA official senior to such director.

Calendar day means every day shown on the calendar.

Food has the meaning given in section 201(f) of the act (21 U.S.C. 321(f)). Examples of food include, but are not limited to, fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or components of food,

animal feed, including pet food, food and feed ingredients and additives, including substances that migrate into food from food packaging and other articles that contact food, dietary supplements and dietary ingredients, infant formula, beverages, including alcoholic beverages and bottled water, live food animals, bakery goods, snack foods, candy, and canned foods.

Perishable food means food that is not heat-treated; not frozen; and not otherwise preserved in a manner so as to prevent the quality of the food from being adversely affected if held longer than 7 days under normal shipping and storage conditions.

We means the United States Food and Drug Administration (FDA).

Working day means any day from Monday through Friday, excluding federal holidays.

You means any person who received the detention order or that person's representative.

§ 1.378 What criteria does FDA use to order a detention?

An officer or qualified employee of FDA may order the detention of any article of food that is found during an inspection, examination, or investigation under the act if the officer or qualified employee has credible evidence or information indicating that the article of food presents a threat

of serious adverse health consequences or death to humans or animals.

§ 1.379 How long may FDA detain an article of food?

(a) FDA may detain an article of food for a reasonable period that may not exceed 20 calendar days after the detention order is issued. However, an article may be detained for 10 additional calendar days if a greater period of time is required to institute a seizure or injunction action. The authorized FDA representative may approve the additional 10 calendar day detention period at the time the detention order is issued or at any time within the 20 calendar day period by amending the detention order.

(b) The entire detention period may not exceed 30 calendar days.

(c) An authorized FDA representative may, in accordance with § 1.384, terminate a detention order before the expiration of the detention period.

§ 1.380 Where and under what conditions must the detained article of food be held?

(a) You must hold the detained article of food in the location and under the conditions specified by FDA in the detention order.

(b) If FDA determines that removal to a secure facility is appropriate, the article of food must be removed to a secure facility. A detained article of food remains under detention before, during, and after movement to a secure facility. FDA will also state in the detention order any conditions of transportation applicable to the detained article.

(c) If FDA directs you to move the detained article of food to a secure facility, you must receive a limited conditional release under § 1.381(c) before you ~~may not~~ move the detained article of food to a secure facility ~~unless you have received a limited conditional release under § 1.381(c)~~.

(d) You must ensure that any required tags or labels under § 1.382 accompany the detained article during and after movement. The tags or labels must remain with the article of food until FDA terminates the detention order or the detention period expires, whichever occurs first, unless otherwise permitted by the authorized FDA representative.

(e) The movement of an article of food in violation of a detention order issued under § 1.393 is a prohibited act under section 301 of the act.

§ 1.381 May a detained article of food be delivered to another entity or transferred to another location?

(a) An article of food subject to a detention order under this subpart may not be delivered to another entity pursuant to the execution of a bond. Notwithstanding section 801(b) of the act (21 U.S.C. 381(b)), while any article of food is subject to a detention order under section 304(h), it may not be delivered to any of its importers, owners, or consignees.

(b) Except as provided in subsection (c), no person may transfer a detained article of food within or from the place where it has been ordered detained, or from the place to which it was removed, until an authorized FDA representative releases the article of food under § 1.384 or the detention period expires under § 1.379, whichever occurs first.

(c) The authorized FDA representative may approve, in writing, a request for a limited conditional release of a detained article of food for any of the following purposes:

(1) To destroy the article of food;

(2) To move the detained article of food to a secure facility pursuant to the terms of a detention order;

(3) To maintain or preserve the integrity or quality of the article of food; or

(4) For any other purpose that the authorized FDA representative believes is appropriate in the case.

(d) You must submit your request for the limited conditional release of the detained article in writing to the authorized FDA representative who approved the detention order. You must state in your request the reasons for movement; the exact address of and location in the new facility (or the new location within the same facility) where the detained article of food will be transferred; an explanation of how the new address and location will be secure, if FDA has directed that the article be detained in a secure facility; and how the article will be held under any applicable conditions described in the detention order. If you are requesting a limited conditional release for the purpose of destroying the detained article of food, you also must submit a verified statement identifying the ownership or proprietary interest you have in the detained article of food, in accordance with Supplemental Rule C to the Federal Rules of Civil Procedure.

(e) If FDA approves a request for limited conditional release, the article may be transferred but remains under detention before, during, and after the transfer. FDA will state any conditions of transportation applicable to the detained article. You may not transfer a detained article of food without

FDA supervision unless FDA has declined in writing to supervise the transfer. If FDA has declined in writing to supervise the transfer of a detained article, you must immediately notify in writing the authorized FDA representative who approved the limited conditional release of the article of food that the article of food has reached its new location, and the specific location of the detained article within the new location. Such written notification may be in the form of a fax or email or other form as agreed to by the authorized FDA representative.

(f) You must ensure that any required tags or labels under § 1.382 accompany the detained article during and after movement. The tags or labels must remain with the article of food until FDA terminates the detention order or the detention period expires, whichever occurs first, unless otherwise permitted by the authorized FDA representative who approves the limited conditional release of the detained article of food under this section.

(g) The transfer of an article of food in violation of a detention order issued under § 1.393 is a prohibited act under section 301 of the act.

§ 1.382 What labeling or marking requirements apply to a detained article of food?

The officer or qualified employee of FDA issuing a detention order under § 1.393 may label or mark the detained article of food with official FDA tags or labels that include the following information:

(a) A statement that the article of food is detained by the United States Food and Drug Administration in accordance with section 304(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334(h));

(b) A statement that the article of food must not be consumed, moved, altered, or tampered with in any manner for the period shown, without the written permission of an authorized FDA representative;

(c) A statement that the violation of a detention order or the removal or alteration of the tag or label is a prohibited act, punishable by fine or imprisonment or both ; and

(d) The detention order number, the date and hour of the detention order, the detention period, and the name of the officer or qualified employee of FDA who issued the detention order.

§ 1.383 What expedited procedures apply when FDA initiates a seizure action against a detained perishable food?

If FDA initiates a seizure action under section 304(a) of the act against a perishable food subject to a detention order under this subpart, FDA will send the seizure recommendation to the Department of Justice within 4 calendar days after the detention order is issued, unless extenuating circumstances exist. If the fourth calendar day is not a working day, FDA will advise the Department of Justice of its plans to recommend a seizure action on the last working day before the fourth calendar day and send the recommendation as soon as practicable on the first working day that follows. For purposes of this section, an extenuating circumstance includes, but is not limited to, instances when the results of confirmatory testing or other evidentiary development requires more than 4 calendar days to complete.

§ 1.384 When does a detention order terminate?

If FDA terminates a detention order or the detention period expires, an authorized FDA representative will issue a detention termination notice releasing the article of food to any person who received the detention order or that person's representative and will remove, or authorize in writing the removal of, the required labels or tags. If FDA fails to issue a detention

termination notice and the detention period expires, the detention order is deemed to be terminated.

How does FDA order a detention?

§ 1.391 Who approves a detention order?

An authorized FDA representative, i.e., the FDA District Director in whose district the article of food involved is located or an FDA official senior to such director, must approve a detention order. If prior written approval is not feasible, prior oral approval must be obtained and confirmed in writing as soon as possible.

§ 1.392 Who receives a copy of the detention order?

(a) FDA must issue the detention order to the owner, operator, or agent in charge of the place where the article of food is located. If the owner of the article of food is different from the owner, operator, or agent in charge of the place where the article is detained, FDA must provide a copy of the detention order to the owner of the article of food if the owner's identity can be determined readily.

(b) If FDA issues a detention order for an article of food located in a vehicle or other carrier used to transport the detained article of food, we also must provide a copy of the

detention order to the shipper of record and the owner and operator of the vehicle or other carrier, if their identities can be determined readily.

§ 1.393 What information must FDA include in the detention order?

(a) FDA must issue the detention order in writing, in the form of a detention notice, signed and dated by the officer or qualified employee of FDA who has credible evidence or information indicating that such article of food presents a threat of serious adverse health consequences or death to humans or animals.

(b) The detention order must include the following information:

(1) The detention order number;

(2) The date and hour of the detention order;

(3) Identification of the detained article of food;

(4) The period of the detention;

(5) A statement that the article of food identified in the order is detained for the period shown;

(6) A brief, general statement of the reasons for the detention;

(7) The address and location where the article of food is to be detained and the appropriate storage conditions;

(8) Any applicable conditions of transportation of the detained article of food;

(9) A statement that the article of food is not to be consumed, moved, altered, or tampered with in any manner during the detention period, unless subject to a limited conditional release under § 1.381;

(10) The text of section 304(h) of the act and §§ 1.401 and 1.402 of this chapter;

(11) A statement that any informal hearing on an appeal of a detention order must be conducted as a regulatory hearing under part 16 of this chapter, with certain exceptions described in § 1.403;

(12) The mailing address, telephone number, email address, and fax number of the FDA district office and the name of the FDA District Director in whose district the detained article of food is located; and

(13) A statement indicating the manner in which approval of the detention order was obtained, i.e., orally or in writing.

What is the appeal process for a detention order?

§ 1.401 Who is entitled to appeal?

Any person who would be entitled to be a claimant for the article of food, if seized under section 304(a) of the act, may appeal a detention order as specified in § 1.402. Procedures for establishing entitlement to be a claimant for purposes of section 304(a) of the act are governed by Supplemental Rule C to the Federal Rules of Civil Procedure.

§ 1.402 What are the requirements for submitting an appeal?

(a) If you want to appeal a detention order, you must submit your appeal in writing to the FDA District Director, in whose district the detained article of food is located, at the mailing address, email address, or fax number identified in the detention order according to the following applicable timeframes:

(1) Perishable food: If the detained article is a perishable food, as defined in § 1.377, you must file an appeal within two (2) calendar days of receipt of the detention order.

(2) Non-perishable food: If the detained article is not a perishable food, as defined in § 1.377, you must file a notice of an intent to request a hearing within four (4) calendar days of receipt of the detention order. If the notice of intent is not filed within four calendar days, you will not be granted a hearing. If you have not filed a

timely notice of intent to request a hearing, you may file an appeal without a hearing request. Whether or not it includes a request for hearing, your appeal must be filed within ten (10) calendar days of receipt of the detention order.

(b) Your request for appeal must include a verified statement identifying your ownership or proprietary interest in the detained article of food, in accordance with Supplemental Rule C to the Federal Rules of Civil Procedure.

(c) The process for the appeal of a detention order under this section terminates if FDA institutes either a seizure action under section 304(a) of the act or an injunction under section 302 of the act regarding the article of food involved in the detention order.

(d) As part of the appeals process, you may request an informal hearing. Your request for a hearing must be in writing and must be included in your request for an appeal specified in paragraph (a) of this section. If you request an informal hearing, as defined in section 201(x) of the act, and FDA grants your request, the hearing will take place according to the following applicable timeframes:

(1) Perishable food: If the detained article is a perishable food, as defined in § 1.377, the hearing will be

held within two (2) calendar days after the date the appeal is filed.

(2) Non-perishable food: If the detained article is not a perishable food, as defined in § 1.377, the hearing will be held within three (3) calendar days after the date the appeal is filed.

§ 1.403 What requirements apply to an informal hearing?

If FDA grants a request for an informal hearing on an appeal of a detention order, FDA must conduct the hearing in accordance with part 16 of this chapter, except that:

(a) The detention order under § 1.393, rather than the notice under § 16.22(a) of this chapter, provides notice of opportunity for a hearing under this section and is part of the administrative record of the regulatory hearing under § 16.80(a) of this chapter.

(b) A request for a hearing under this section must be addressed to the FDA District Director in whose district the article food involved is located.

(c) The provision in § 16.22(b) of this chapter, providing that a person not be given less than three (3) working days after receipt of notice to request a hearing, does not apply to a hearing under this subpart.

(d) The provision in § 16.24(e) of this chapter, stating that a hearing may not be required to be held at a time less than two (2) working days after receipt of the request for a hearing, does not apply to a hearing under this subpart.

(e) Section 1.406, rather than §16.24(f) of this chapter, describes the statement that will be provided to an appellant where a detention order is based on classified information.

(f) Section 1.404, rather than § 16.42(a) of this chapter, describes the FDA employees, e.g., regional food and drug directors or other officials senior to a district director, who preside at hearings under this subpart.

(g) The presiding officer may require that a hearing conducted under this section be completed within one day, as appropriate.

(h) Provisions of Part 16 that provide for the presiding officer to issue a report and recommended decision only do not apply. The presiding officer will issue the final agency decision.

§ 1.404 Who serves as the presiding officer at an informal hearing?

The presiding officer of an informal hearing on an appeal of a detention order, who also must decide the appeal, must be an

FDA regional food and drug director or another official senior to an FDA district director.

§ 1.405 When does FDA have to issue a decision on an appeal?

(a) The presiding officer must issue a decision confirming or revoking the detention within five (5) calendar days after the appeal is filed. If FDA either fails to provide you with an opportunity ~~for~~ to request an informal hearing, or fails to confirm or terminate the detention order within the 5-day period, the detention order is deemed terminated.

(b) If you appeal the detention order but do not request an informal hearing, the presiding officer must issue a decision on the appeal confirming or revoking the detention within five (5) calendar days after the date the appeal is filed. If the presiding officer fails to confirm or terminate the detention order during such 5-day period, the detention order is deemed terminated.

(c) If you appeal the detention order and request an informal hearing and your hearing request is denied, the presiding officer must issue a decision on the appeal confirming or revoking the detention within five (5) calendar days after the date the appeal is filed. If the presiding officer fails to

confirm or terminate the detention order during such 5-day period, the detention order is deemed terminated.

(d) If the presiding officer confirms a detention order, the article of food continues to be detained until we terminate the detention under § 1.384 or the detention period expires under § 1.379, whichever occurs first.

(e) If the presiding officer terminates a detention order, or the detention period expires, FDA must terminate the detention order as specified under § 1.384.

(f) Confirmation of a detention order by the presiding officer is considered a final agency action for purposes of section 702 of title 5, United States Code.

§ 1.406 How will FDA handle classified information in an informal hearing?

Where the credible evidence or information supporting the detention order is classified under the applicable Executive Order as requiring protection from unauthorized disclosure in the interest of national security ("classified information"), FDA will not provide you with this information. The presiding officer will give you notice of the general nature of the information and an opportunity to offer opposing evidence or information, if he or she may do so consistently with

safeguarding the information and its source. If classified information was used to support the detention, then any confirmation of such detention will state whether it is based in whole or in part on that classified information.

Part 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

3. The authority citation for 21 CFR part 16 continues to read as follows:

Authority: 15 U.S.C. 1451-1461; 21 U.S.C. 141-149, 321-394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201-262, 263b, 364.

4. Amend § 16.1 ~~to revise paragraph (b)(1) to read as~~ follows:

Re done per OFR Kent Giles bb 4-28

§ 16.1 Scope.

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(a) * * *

(b) * * *

(1) Statutory provisions:

Section 304(g) of the act relating to the administrative detention of devices (see § 800.55(g) of this chapter).

Section 304(h) of the act relating to the administrative detention of food for human or animal consumption (see part 1, subpart K of this chapter).

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Dated

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